

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and remarks.

### **Status of the Claims**

Claims 1, 3, 12, and 23 are currently amended, claims 24-31 are new, and claim 14 is canceled without prejudice or disclaimer. Currently Amended claim 1 finds support throughout the as-filed application at, for example, Examples 1 and 2, as well as page 37, line 34 thru page 38, line 17. New claims 24-31 are supported by the original application, at, for example, Example 1, page 3, line 36 thru page 4, line 14; page 4, lines 21-24; page 4, lines 19-20; as well as in existing claims 3, 12, and 23. No new matter has been added.

Upon entry of this amendment, claims 1, 3, 12, 23, and 24-31 are pending and presented for examination.

### **Rejections under 35 U.S.C. § 112, first paragraph**

Claims 1, 3, 12, 14, and 23 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Office Action, item 7, pages 3-4. Specifically, the PTO alleges the specification “while being enabling for an antigen-specific dendritic cell pulsed by an HM1.24 protein or an HM1.24 peptide, does not reasonably provide enablement for a cancer vaccine containing as an active ingredient an antigen-specific dendritic cell pulsed by an HM1.24 protein or an HM1.24 peptide.” *Id.* at page 3. In so doing, the PTO states “Because the definition for the term ‘vaccine’ is a preparation for preventing a disease, the invention is directed to a composition for preventing a cancer.” *Id.*

While not acquiescing on the merits, the present version of claims 1, 3, 12, 14, and 23 should avoid the PTO’s concerns. Applicants respectfully reconsideration and withdrawal of the rejection.

**Claim Objection**

Claim 14 is objected for alleged language informalities. Office Action, item 8, page 4. Applicants thank Examiner Sang for indicating that claim 14 duplicates claim 12. Accordingly, claim 14 is canceled without prejudice or disclaimer.

**Rejections under 35 U.S.C. § 103, first paragraph**

**A. Treon *et al.*, in view of Ohtomo *et al.* and Chiriva-Internati *et al.***

Claims 1, 12, and 14 are rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Treon *et al.*, in view of Ohtomo *et al.* and Chiriva-Internati *et al.* Office Action, item 10, pages 4-6. Specifically, the PTO alleges “Treon *et al.* teach that HM1.24 is one of the typical candidate targets for antibody-mediated therapy of MM (see page 599, left column line 3). *Id.* at page 5. Yet the PTO acknowledges “Treon *et al.* do not specifically describe dendritic cells pulsed with HM1.24 antigen.” *Id.* To remedy Treon’s admitted deficiencies, the PTO relies on Ohtomo *et al.* and Chiriva-Internati *et al.* Applicants respectfully traverse the grounds for this rejection.

For a proper combination of references, there must be some teaching or suggestion in the prior art. MPEP § 2142. Thus, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP § 2143.01.

Furthermore, even if there were suggestion for such a combination, the combined teachings would not result in the claimed invention. To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03.

As a starting point, Treon *et al.* neither alone nor together with Ohtomo *et al.* and Chiriva-Internati *et al.* suggests whether or not dendritic cells can be pulsed by Idiotypic Vaccination using the HM1.24 protein or the HM1.24 peptide, or whether or not the HM1.24 protein or the HM1.24 peptide can be used for immune therapy. The silence of these references surely cannot be taken as an admission that dendritic cells can be pulsed by

Idiotypic Vaccination using the HM1.24 protein or HM1.24 peptide, or whether or not the HM1.24 protein or HM1.24 peptide can be used for immune therapy. For this reason alone, the rejection of claims 1, 12, and 14 is improper and should be withdrawn.

Furthermore, and as explained by Treon *et al.*, Idiotypic Vaccination and DNA vaccines are different therapies and thus are not fungible. *See Treon et al.*, pages 604-605. Because the present invention embraces dendritic cells pulsed by the HM1.24 protein or HM1.24 peptide, the present invention provides Idiotypic Vaccination. In stark contrast, Chiriva-Internati *et al.* discloses that dendritic cells can be pulsed by introducing an HM1.24 gene into the dendritic cells as a DNA vaccine. Because Idiotypic Vaccination and DNA Vaccine differ in their action mechanisms, and are therefore not fungible, it is not surprising that Chiriva-Internati *et al.* fails to teach or suggest dendritic cells pulsed by Idiotypic Vaccination using the HM1.24 protein or the HM1.24 peptide. That is, from the disclosure of Chiriva-Internati *et al.*, one of ordinary skill in the art would have no credible basis to extrapolate whether or not the HM1.24 protein or the HM1.24 peptide would work in Idiotypic Vaccination.

Moreover, no combination of Treon *et al.*, Ohtomo *et al.*, and Chiriva-Internati *et al.*, teach or suggest whether mature dendritic cells can be obtained by pulsing immature dendritic cells with the HM1.24 protein or the HM1.24 peptide. Because each cited reference is silent on this point, no combination of these three references could lead one of ordinary skill in the art to use the HM1.24 protein or the HM1.24 peptide for Idiotypic Vaccination by pulsing immature dendritic cells so as to obtain mature dendritic cells, which can be administered to a patient.

For at least these reasons, no permutation of Treon *et al.*, Ohtomo *et al.*, and Chiriva-Internati *et al.*, would render the present invention obvious, and therefore, the rejection should be withdrawn.

**B. Treon *et al.*, Ohtomo *et al.*, and Chiriva-Internati *et al.*, and further in view of WO 200177362, as evidenced by Porgador *et al.***

Claims 1, 3, 12, 14, and 23 are rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Treon *et al.*, in view of Ohtomo *et al.*, and Chiriva-Internati *et al.*, and in further in view of WO 200177362, as evidenced by Porgador *et al.* Office Action, item 11, pages 6-7. While the PTO acknowledges “Treon, Ohtomo, and Chiriva-Internati do not teach pulsing dendritic cells with the soluble HM1.24 that is SEQ ID NO: 16 or 17.” *Id.* at page 7. However, the PTO alleges “these deficiencies are made up for in the teachings of WO 200177362 and Porgador *et al.*” *Id.* Applicants respectfully traverse the grounds for this rejection.

As discussed above, no permutation of Treon *et al.*, Ohtomo *et al.*, and Chiriva-Internati *et al.* would render the present invention obvious because each fails to disclose dendritic cells pulsed by Idiotypic Vaccination using the HM1.24 protein or the HM1.24 peptide. This deficiency is not cured by WO 200177362, as evidenced by Porgador *et al.*, because these references also fail to disclose dendritic cells pulsed by Idiotypic Vaccination using the HM1.24 protein or the HM1.24 peptide. Accordingly, the rejection of claims 3 and 23 is improper and should be withdrawn.

### CONCLUSION

Applicants believe that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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